Editorial

Botulinum Toxin for Refractory Trigeminal Neuralgia: A Trial Sequential Analysis of Randomized Clinical Trials

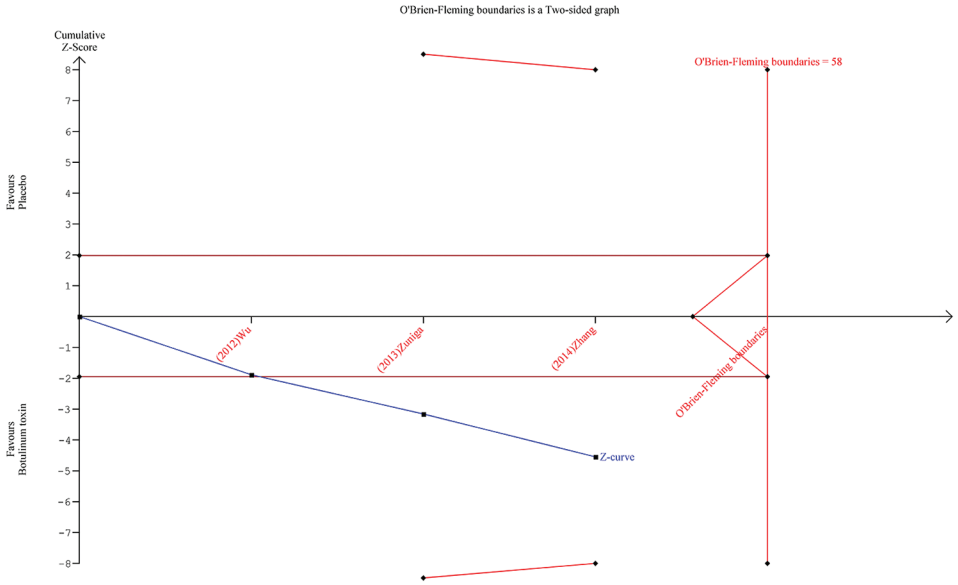

Figure 1: Trial sequential analysis of botulinum toxin compared to placebo for number of patients with pain relief. Blue line indicates the trend in the pooled estimates with addition of results from each trial, and the final pooled estimates were observed to favor botulinum toxin

In this issue, Caldera *et al*.[1] published a study where the authors observed a significant reduction in the symptoms of trigeminal neuralgia (TN) following injection of botulinum toxin at the trigger point in a cohort of South Asian patients. In our earlier network meta-analysis of interventions for refractory TN, we also observed that botulinum toxin injection was associated with significant benefits compared to placebo.[2] A previous systematic review assessing the prospective studies on botulinum toxin in TN observed therapeutic response ranging between 70% and 100% without any significant major adverse events.[3] Although botulinum toxin is approved only for treating chronic migraine, the analgesic effects of botulinum toxin in TN have already been reported first in 1998. Since then, numerous nonrandomized and observational studies and four randomized controlled clinical trials[4-7] have been conducted with botulinum toxin in refractory TN. We carried out a trial sequential analysis[8] assessing the efficacy of botulinum toxin from the estimates of three randomized clinical trials[4-6] with the methodology described similarly elsewhere.[7] Relative risk (95% confidence intervals) of patients with pain relief was the outcome variable, and one study[7] did not report this outcome. We observed statistically significant pooled estimates (2.86 [1.82, 4.48]) favoring botulinum toxin [Figure 1], and the trial sequential analysis confirmed the existence of adequate evidence for therapeutic utility of botulinum toxin. Although there is no expert consensus on using botulinum toxin in refractory TN due to lack of robust and long-term follow-up studies and cost-effectiveness data, the agent looks promising to use based on trial sequential analysis principles.

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